#26

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Turner, Jr. and Mathur

Serial No.:	09/714,883	Group Art Unit:	1646
Filed:	11/16/2000	Examiner:	O. Chernyshev
For:	Novel Human Secreted Proteins and Polynucleotides Encoding the Same	Attorney Docket No.:	LEX-0092-USA

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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REPLY BRIEF

Sir:

Appellants hereby submit an original and two copies of this Reply Brief to the Board of Patent Appeals and Interferences ("the Board") in response to the Examiner's Answer mailed on April 9, 2003 (Paper Number 22). This Reply Brief is timely submitted in light of the concurrently filed Petition for an Extension of Time of two months to and including August 9, 2003, which falls on a Saturday and is therefore extended until Monday, August 11, 2003 under 37 C.F.R. § 1.7, and authorization to deduct the fee as required under 37 C.F.R. § 1.17(a)(2) from Appellants' Representatives' deposit account.

Appellants believe no fees in addition to the fee for the extension of time are due in connection with this Reply Brief. However, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to this communication, the Commissioner is authorized to charge any underpayment or credit any overpayment to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

I. REAL PARTY IN INTEREST

Appellants agree with the Examiner's assertion that "(a) statement identifying the real party in interest is contained in the brief" (Examiner's Answer at page 1).

II. RELATED APPEALS AND INTERFERENCES

Appellants agree with the Examiner's assertion that "(a) statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief" (Examiner's Answer at page 2).

III. STATUS OF THE CLAIMS

Appellants agree with the Examiner's assertion that "(t)he statement of the status of the claims contained in the brief is correct" (Examiner's Answer at page 2).

IV. STATUS OF THE AMENDMENTS

Appellants agree with the Examiner's assertion that "(t)he appellant's statement of the status of the amendments after final rejection contained in the brief is correct" (Examiner's Answer at page 2).

V. SUMMARY OF THE INVENTION

Appellants agree with the Examiner's assertion that "(t)he summary of invention contained in the brief is correct" (Examiner's Answer at page 2).

VI. ISSUES ON APPEAL

Appellants agree with the Examiner's assertion that "(t)he appellant's statement of the issues in the brief is correct" (Examiner's Answer at page 2).

VII. GROUPING OF THE CLAIMS

Appellants agree with the Examiner's assertion that "Appellant's brief includes a statement that the claims stand or fall together" (Examiner's Answer at page 2).

VIII. CLAIMS APPEALED

Appellants agree with the Examiner's assertion that "(t)he copy of the appealed claims contained in the Appendix to the brief is correct" (Examiner's Answer at page 2).

IX. PRIOR ART OF RECORD

Appellants agree with the Examiner's assertion that "(n)o prior art is relied upon by the examiner in the rejection of the claims under appeal" (Examiner's Answer at page 2).

X. ARGUMENT

A. Do Claims 1-3 Lack a Patentable Utility?

Appellants do not wish to restate all of the arguments presented in the Appeal Brief concerning the

Examiner's allegation that claims 1-3 lack a patentable utility, and instead incorporate the entirety of Section VIII(A) of the Amended Appeal Brief at this point herein by reference. However, Appellants are compelled to specifically address two arguments presented in the Examiner's Answer for the record. Furthermore, since one of Appellants' asserted utilities was apparently not challenged by the Examiner in the Examiner's Answer, Appellants would like to highlight this issue.

First, Appellants take issue with the Examiner's allegation that "no other art was found to support Appellant's assertion regarding a clear nexus between ceruloplasmins and Wilson's disease" (Examiner's Answer at page 10). In the Amended Appeal Brief, Appellants provided **clear** evidence of a voluminous and steady stream of scientific manuscripts describing the relationship between Wilson's disease and ceruloplasmin, with the first such manuscripts published as early as 1965. This relationship was evidenced by the index of PubMed citations containing the terms Wilson's disease and ceruloplasmin, which was provided in **Exhibit C** of the Amended Appeal Brief. This index listed **562 scientific manuscripts**, a large number of which **directly** concern the relationship between ceruloplasmin and Wilson's disease. Thus, it is **beyond comprehension** that the Examiner could find "no other art ... to support Appellant's assertion regarding a clear nexus between ceruloplasmins and Wilson's disease". Appellants respectfully remind the Examiner that as a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Second, Appellants pointed to a number of additional utilities of the present sequence in the Amended Appeal Brief, including use in a gene chip format to provide a high throughput analysis of the level of gene expression, in determining the genomic structure of the genetic locus encoding the claimed sequence, by defining how the encoded exons are actually spliced together to produce an active transcript, and in mapping the claimed sequence to the corresponding human chromosome. The Examiner's main argument concerning these utilities is that other nucleic acid sequences can be used in a similar fashion ("any naturally occuring (*sic*) polynucleotide can be used in a DNA chip, and thus this asserted utility is not specific"; Examiner's Answer at page 11). In addition to the detailed arguments presented by Appellants in the Amended Appeal Brief with regard to each of these asserted utilities, Appellants point out that the Examiner is clearly confusing the requirement for a **specific** utility, which is the proper standard for utility

under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. As **clearly** stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Importantly, the holding in *Carl Zeiss* is **mandatory legal authority** that is directly applicable to the present appeal, and **directly** rebuts the Examiner's argument. The requirement for a unique utility is not only in conflict with established case law, it is also not the standard adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. **All** batteries have the **exact same** utility - specifically, to provide power. **All** automobile tires have the **exact same** utility - specifically, for use on automobiles. **All** golf balls and golf clubs have the **exact same** utility - specifically, use in the game of golf. **All** cancer treatments have the **exact same** utility - specifically, to treat cancer. **All** anti-infectious agents have the **exact same** broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Finally, Appellants pointed out in the Amended Appeal Brief that the present nucleic acid sequences have utility in forensic analysis (see, for example, the specification from page 10, line 29 through page 11, line 5). As described in the specification at specification at page 13, lines 6-11, a coding region single nucleotide polymorphism, consisting of a G-to-A transition at position 1756 of SEQ ID NO:1, which

can result in the presence of a valine or an isoleucine residue at the corresponding amino acid position 586 of SEQ ID NO:2, was identified in the claimed polynucleotide sequence. As such polymorphisms are the basis for forensic analysis, which in undoubtedly a "real world" utility, the present sequences must in themselves be useful.

Importantly, the Examiner's Answer did not challenge this asserted utility. Appellants respectfully point out that the presently described polymorphism, exactly as it is described in the specification as originally filed, is useful in forensic analysis to specifically identify individual members of the human population based on the presence or absence of the described polymorphism. Simply because the use of this polymorphic marker will necessarily provide additional information on the percentage of particular subpopulations that contain this polymorphic marker does not mean that "additional research" is needed in order for this marker to be of use to forensic science. Using the polymorphic marker as described in the specification as originally field can definitely distinguish members of a population from one another. In the worst case scenario, this marker is useful to distinguish 50% of the population (in other words, the marker being present in half of the population). The ability to eliminate 50% of the population from a forensic analysis clearly is a real world, practical utility. Therefore, any allegation that the use of the presently described polymorphic marker is only potentially useful would be completely without merit, and would not support the alleged lack of utility.

As set forth in detail above, it is important to note that the presence of other or even more useful polymorphic markers for forensic analysis does **not** mean that the use of the presently described polymorphic marker is not a specific utility (*Carl Zeiss Stiftung v. Renishaw PLC, supra*). Further, as the presently described polymorphism is a part of the family of polymorphisms that have a well established utility, Appellants reliance on *In re Brana,* (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*") is directly on point. Additionally, as Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), this should end the issue of the utility of the present claims.

For each of the foregoing reasons, as well as the reasons set forth in the Amended Appeal Brief,

Appellants submit that the rejection of claims 1-3 under 35 U.S.C. § 101 must be overruled.

B. Are Claims 1-3 Unusable Due to a Lack of Patentable Utility?

Regarding the rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by either a clear asserted utility or a well-established utility, Appellants submit that as claims 1-3 have been shown to have "a specific, substantial, and credible utility", as detailed in Section X(A) above, as well as Section VIII(A) of the Appeal Brief, the present rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, cannot stand.

Appellants therefore submit that the rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, must be overruled.

XI. CONCLUSION

Appellants respectfully submit that, in light of the foregoing arguments, as well as the arguments set forth in the Amended Appeal Brief, the conclusion that claims 1-3 lack a patentable utility and are unusable by the skilled artisan due to a lack of patentable utility is unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

Respectfully submitted,

August 11, 2003
Date

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